IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORPORATION,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION — MDL NO. 2326

THIS DOCUMENT RELATES TO

FAYE FOREMAN,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendants.

Case No. 2:13-CV-15591

BOSTON SCIENTIFIC CORPORATION'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT AGAINST PLAINTIFF FAYE FOREMAN

INTRODUCTION

Plaintiff Faye Foreman brings this product liability action against Boston Scientific Corporation ("Boston Scientific") alleging that Boston Scientific's implantable pelvic mesh device – the Advantage Transvaginal Mid-Urethral Sling System ("Advantage") – was defective and caused Ms. Foreman personal injury. Plaintiff's legal theories are without evidentiary or legal support. For the reasons discussed in the incorporated Memorandum, Boston Scientific respectfully moves the Court for an order granting summary judgment on all of Plaintiff's claims.

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STATEMENT OF MATERIAL FACTS

1. Plaintiff Faye Foreman is a citizen and resident of California. Short Form Complaint[1] ("SFC") at ¶¶ 1 and 4.

2. Ms. Foreman experienced stress urinary incontinence ("SUI") for ten years prior to her Advantage sling procedure. August 29, 2014 Deposition of Faye Foreman ("Foreman Dep.")[2] at 100:4-10.

3. Ms. Foreman sought treatment for SUI with Dr. Michael Fogarty on July 15, 2009. Dr. Fogarty noted that Ms. Foreman had severe stress loss with minimal urge. Plaintiff Produced Records[3] ("PLTF Records") 203-204.

4. During the July 15, 2009 visit, Dr. Fogarty also discussed correcting Ms. Foreman's SUI with a transvaginal mesh sling procedure, including the risks associated with that procedure. Ms. Foreman elected to move forward with scheduling the procedure. *Id.*; September 4, 2014 Deposition of Dr. Michael Fogarty ("Dr. Fogarty Dep.")[4] at 88:21-90:1.

5. On August 26, 2009, Ms. Foreman returned to Dr. Fogarty for a pre-operative exam where Dr. Fogarty again discussed the potential risks, benefits and potential complications associated with the mesh sling procedure. PLTF Records 209-211. Dr. Fogarty Dep. 154:9-155:1 Ms. Foreman also signed a consent form that acknowledged that she understood the risks, potential for serious harm and alternative methods of treatment for the mesh sling procedure. PLTF Records 276; Dr. Fogarty Dep. at 155:19-157:6.

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[1] A true and correct copy of the Short Form Complaint is attached to the Motion as Exhibit A.

[2] A true and correct copy of the relevant portions of the August 29, 2014 deposition of Plaintiff Faye Foreman ("Foreman Dep.") is attached to the Motion as Exhibit B.

[3] True and correct copies of the relevant Plaintiff produced records are attached to the Motion as Exhibit C. These records are bates labeled starting with PLTF 000001. Page citations to medical records in this memorandum shall refer to the last two bates numbers on each page.

[4] A true and correct copy of the relevant portions of the September 4, 2014 deposition of Dr. Michael Fogarty ("Dr. Fogarty Dep.") is attached to the Motion as Exhibit D.

6. On September 2, 2009, Ms. Foreman underwent surgery including an urethropexy, cystoscopy, and transvaginal tape procedure utilizing the Advantage sling. The procedure took place at Kaiser Permanente Medical Center in Hayward California. PLTF Records 244-245; SFC at ¶¶ 10-11.

7. The Advantage device is a prescription medical device available only through a licensed physician. Advantage Directions for Use ("Advantage DFU")[5], p.3.

8. The Advantage DFU precautions the physician to "[e]nsure the mesh is placed tension free under the mid-urethra" and that "subsequent infection may require removal of the mesh." Advantage DFU pp. 4-5.

9. The Advantage DFU contains the following Adverse Events: tissue responses including "vaginal erosion/extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, and inflammation," which could require removal of the entire mesh; "[e]xcess tension may cause temporary or permanent lower urinary tract obstruction and retention;" risks of pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder, pelvic and vaginal pain, dyspareunia, vaginal bleeding, and vaginal discharge. Advantage DFU p. 5.

10. The Advantage DFU also warns of the following Potential Complications: irritative voiding symptoms including urgency and urge incontinence, infection, pelvic and vaginal pain, urinary retention, dyspareunia, vaginal bleeding, vaginal discharge, erosion of the vaginal or urethral mucosa or bladder wall, and recurrent stress urinary incontinence. Advantage DFU p.8.

[5] A true and correct copy of the applicable Advantage Transvaginal Mid-Urethral Sling System Directions for Use (English version), is attached to the Motion as Exhibit E.

11. Dr. Fogarty implanted the Advantage sling. SFC at ¶ 12.

12. At the time of Ms. Foreman's surgery, Dr. Fogarty was a board-certified obstetrician/gynecologist. He was been board certified from 1987 until the time he retired in 2011. Dr. Fogarty Dep. 15:5-13.

13. Prior to implanting the Boston Scientific Advantage device in Ms. Foreman, Dr. Fogarty attended many different training and educational opportunities on implanting pelvic mesh devices. *Id.* at 38:12-39:15.

14. Dr. Fogarty has performed more than 500 surgeries involving synthetic slings. Dr. Fogarty Dep. at 124:12-125:3.

15. Dr. Fogarty obtains information about synthetic slings from many different sources such as medical literature, conferences, colleagues, and through his clinical experience. Dr. Fogarty Dep. at 132: 24-133:17.

16. Dr. Fogarty was already aware of the risks in the 2008 FDA Public Health Notification[6] before Ms. Foreman's surgery, including the potential for erosion, infection, pain, urinary problems, recurrence, failure of the procedure, scarring, and decreasing quality of life due to discomfort and pain, and dyspareunia. *Id.* at 161:9-162:13.

17. Dr. Fogarty relies on his own clinical experience and medical training to offer the best treatment option for any particular patient, including Ms. Foreman. *Id.* at 159:21-160:2.

18. Dr. Fogarty does not substitute marketing information for his independent medical judgment. *Id.* at 52:11-13.

19. Ms. Foreman does not recall ever receiving written literature from Boston Scientific prior to her surgery. Foreman Dep. at 124:25-126:2.

[6] A true and correct copy of the 2008 FDA Public Health Notification is attached as Exhibit F.

20. Ms. Foreman relied on Dr. Fogarty's medical judgment to evaluate the risks and benefits of the Advantage for her. *Id.* at 126:8-14.

21. Ms. Foreman trusted Dr. Fogarty's recommendation that the Advantage was a safe and appropriate treatment option. *Id.* at 126:16-21.

22. Ms. Foreman understood there were risks involved with the procedure and she accepted those risks. *Id.* at 140:5-13.

23. Ms. Foreman understood the sling would be permanently implanted in her body. *Id.* at 131:19-21.

24. Plaintiff filed this action against Boston Scientific on June 25, 2013. *See* SFC.

25. Plaintiff asserts claims for negligence, strict liability (design defect, manufacturing defect, and failure to warn), breach of express warranty, breach of implied warranty, fraudulent concealment, and punitive damages. *Id.* at ¶ 13.

26. As a result of implantation of the Advantage, Ms. Foreman alleges she has suffered from urinary incontinence, general pain, pain with intercourse, mesh exposure, vaginal shrinkage and bowel problems. First Amended Plaintiff Fact Sheet[7] ("FAPFS") p. 5.

APPLICABLE LAW

For implantable medical device cases that originate elsewhere, this Court applies the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, at *1-5 (S.D. W. Va. Jan. 17, 2014) (ECF No. 55). *See also In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 2011 WL 1375011, at *6 ("[T]he better approach is to treat foreign direct filed cases as if they were transferred from a judicial district sitting in the state where the case originated," which

[7] A true and correct copy of Plaintiff's First Amended Fact Sheet is attached to the Motion as Exhibit G.

is "the state where the plaintiff purchased and was prescribed the subject drug."); *In re Avandia Mktg, Sales Practices & Prods. Liab. Litig.*, MDL No. 1871, 2012 WL 3205620, at *2 (E.D. Pa. Aug. 7, 2010) ("The Court has concluded, as have other MDL courts, that such cases should be governed by the law of the states where Plaintiff received treatment and prescriptions for Avandia. This ruling will promote uniform treatment between those Plaintiffs whose cases were transferred into the MDL from their home states and those Plaintiffs who filed directly in the MDL."). Ms. Foreman's surgeries with the Advantage pelvic mesh device were in California. As a result, this Court should apply California's choice-of-law rules. Using this framework, California substantive law applies to Ms. Foreman's compensatory damages claims.

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact" and that Boston Scientific is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Summary judgment is not a "disfavored procedural shortcut," but a useful tool for disposing of insubstantial claims. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

While the Court must view the facts and draw inferences in the manner most favorable to the non-moving party, the existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the non-moving party must affirmatively set forth facts showing there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact for trial. *Id.* at 256. When the non-moving party bears the burden of proving the claim or defense, the moving party can meet its

burden by pointing out the absence of evidence of a genuine issue of material fact from the non-moving party. *Musick v. Burke*, 913 F.2d 1390, 1394 (9th Cir. 1990). The moving party need not disprove the other party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986).

Summary Judgment is appropriate here because the record establishes that Plaintiff cannot recover on any of her claims as a matter of law.[8]

ARGUMENT

I. PLAINTIFF'S STRICT LIABILITY, NEGLIGENCE AND FRAUDULENT CONCEALMENT CLAIMS FAIL

a. Plaintiff's Design Defect Claims Are Barred in California.

Claims for strict liability design defect are not cognizable in California implantable medical device cases. *Garrett v. Howmedica Osteonics Corporation*, 214 Cal. App. 4th 173, 183-85 (Cal. Ct. App. 2013) (prosthetic bone); *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1397 (Cal. Ct. App. 1994) (breast implant); *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 360 (Cal. Ct. App. 1992) (intrauterine device); *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 11 (Cal. Ct. App. 1992) (penile prosthesis); *see also Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 595 (Cal. Ct. App. 1996) (jelly-like fluid used in optical surgery).

In *Brown v. Superior Court*, the California Supreme Court enumerated multiple policy reasons for eliminating such claims, including encouraging the development and availability of medical products. 44 Cal. 3d 1049, 1069 (Cal. 1988). In *Hufft*, the California Court of Appeal explained that these "compelling policy reasons" apply with equal force in the implanted medical device context. 4 Cal. App. 4th at 11. Here, Plaintiff' claim against Boston Scientific for strict liability-design defect relates to the implantation of the Advantage device. (Statement of Material

[8] Boston Scientific has filed a separate Motion for Summary Judgment Based on Statute of Limitations. Boston Scientific incorporates those arguments by reference here and maintains that it is entitled to summary judgment on the grounds of the statute of limitations alone.

Facts ("SOMF") Nos. 11 and 25.) Because California law precludes strict liability for a design defect in a medical device, Plaintiff's design defect claim must be dismissed as a matter of law.

Plaintiff's negligence claim also fails because it suffers from the same problems of proof and legal obstacles as the strict liability theories: it must be dismissed under the learned intermediary doctrine (as discussed below) or as reiteration of a design defect claim that does not exist as a matter of California law.[9] *See DeLeon v. Commercial Mfg. & Supply Co.*, 195 Cal. Rptr. 867, 875 (Cal. Ct. App. 1983) (in product design cases, strict liability and negligence claims merge: "With only slight editing we could take our discussion of the strict liability cause of action and convert it into the language of negligence. The same summary judgment rationale applies when the products liability window dressing is removed."). *Brown* (reiterated in *Garrett*, 214 Cal. App. 4th at 182-83) specifically held that the risk/benefit analysis was inapplicable to products cases involving medical devices. 44 Cal. 3d at 1063-64. California juries are not put in the position of discerning the overall risks and benefits of medical devices, or whether they should remain available for sale, in the context of individual cases, which is exactly what a design defect claim requires, whether sounding in strict liability or negligence.

b. Plaintiff's Manufacturing Defect Claim Fails for Lack of Evidence.

To sustain a strict liability manufacturing defect claim under California law, a plaintiff must offer evidence that the product differed "from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker v. Lull Engineering Corp.*, 20 Cal. 3d 413, 429 (Cal. 1978); *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 613

[9] Also, there is no separate "duty to test" claim under California law. *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1488 (Cal. Ct. App. 1999) (breast implant) (affirming directed verdict on failure to test claim). Similarly, no California law supports the existence of a separate "duty to train" claim in the context of prescription medical device and products liability. *See generally Chamian v. Sharplan Lasers, Inc.*, 2004 WL 2341569, at *7 (Mass. Super. Ct. Sept. 24, 2004) ("[A] manufacturer should be able to presume mastery of basic operations by experts or skilled professionals . . . and should not owe a duty to warn or instruct such persons on how to perform basic operations.").

(Cal. Ct. App. 2002) (noting that the "focus is on whether the particular product involved in the incident was manufactured in conformity with the manufacturer's design."). Plaintiff has never offered evidence that the Advantage device at issue differed from other units of the same product line. Their expert reports make no suggestion that Ms. Foreman's complaints stem from a manufacturing issue with her particular device. *See Jones v. C.R. Bard, Inc.*, No. 2:11-cv-00114, at *6-8 (S.D. W. Va. June 4, 2013) (ECF No. 288) (analyzing plaintiffs' experts' theories and finding they pertain to design, not manufacturing, defect allegations). Therefore, Boston Scientific is entitled to summary judgment on Plaintiff's strict liability manufacturing defect claim.

c. Plaintiff's Warnings Claims Fail.

1. Plaintiff's Warnings Claims Fail under the Learned Intermediary Doctrine.

Whether sounding in strict liability, negligence, breach of express or implied warranty, or fraudulent concealment, the gravamen of Plaintiff's Complaint is that Boston Scientific failed to warn about the Advantage device's risks.[10] The learned intermediary doctrine thus extends to and bars all of Plaintiff's claims, including their fraud-based claims.[11] Plaintiff cannot establish

[10] *See, e.g.*, *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116, 920 P.2d 1347 (1996) ("[T]he duty to warn runs to the physician, not to the patient."); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 986, 989 (C.D. Cal. 2001), *aff'd,* 358 F.3d 659, 660-61 (9th Cir. 2004) (wrongful death, negligence, survival action, fraud, breach of warranty); *Huntman v. Danek Med. Inc*., No. 97-cv-2155, 1998 WL 663362, at *1 (S.D. Cal. July 24, 1998) (strict liability, negligence, fraud, breach of warranty); *Lord v. Sigueiros*, No. CV040243, 2006 WL 1510408, at *1 (Cal. Super. Ct. Apr. 25, 2006) (negligence, strict liability, breach of implied warranty, breach of express warranty, intentional infliction of emotional distress, fraud); *Rivas v. Safety-Kleen Corp.*, 98 Cal. App. 4th 218, 231 (Cal. Ct. App. 2002) (finding that plaintiff's fraud claim ". . . was merely the failure to warn claim recast as a claim for fraudulent concealment.").

[11] This is, likewise, the conclusion drawn by jurisdictions across the country. *See, e.g.*, *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997), *aff'd sub nom.*, 165 F.3d 374 (5th Cir. 1999) (finding that learned intermediary doctrine of all states apply to claims of strict liability, negligence, misrepresentation, and implied warranty); *Talley v. Danek*, 179 F.3d 154, 163 (4th Cir. 1999) (affirming dismissal on learned intermediary doctrine's application to breach of warranty and fraud claims, noting that they were essentially failure to warn claims); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999) (affirming dismissal on learned intermediary doctrine's application to breach of warranty claim); *Wilson v. Upjohn Corp.*, 968 F.2d 1217 (6th Cir. 1992) (affirming dismissal on learned intermediary doctrine's application to strict liability and negligence claims); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1372-73 (S.D. Fla. 2007) (finding that claims for

the essential element of proximate causation – that the inadequacy or absence of a warning caused Plaintiff's injury – because there is no evidence that Dr. Fogarty relied upon the warnings in the Advantage DFU. Rather, he relied on his independent medical judgment and experience. (SOMF Nos. 13-15 and 17.) Therefore, any change to the warnings would not have prevented Ms. Foreman's claimed injuries.

Because California applies the learned intermediary doctrine, Boston Scientific had a duty to warn only Dr. Fogarty, Ms. Foreman's prescribing physician, not Ms. Foreman. *See Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116 (Cal. 1996). Where the learned intermediary doctrine applies, a plaintiff must prove "not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of the warning caused the [plaintiff's] injury," and a plaintiff cannot meet this burden when her physician did not rely upon the labeling at issue. *Motus*, 196 F. Supp. 2d at 991; *see also Latiolais v. Merck & Co., Inc.*, 302 F. App'x 756, 757 (9th Cir. 2008) (affirming summary judgment when plaintiff did not prove that a different warning would have been read or heeded by the prescribing physician). "If an adequate warning is received by the person to whom the law requires that the warning be given, the manufacturer may assume that it will be read and heeded." *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 991 (Cal. Ct. App. 1971).

Summary judgment is warranted on Plaintiff's failure to warn claim under the learned intermediary doctrine because Plaintiff cannot establish proximate causation. Twice in circumstances closely akin to this case, this Court has considered summary judgment motions

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negligence/gross negligence, strict products liability, and negligent misrepresentation "are all ultimately based upon Biomet's alleged failure to warn."); *Catlett v. Wyeth*, 379 F. Supp. 2d 1374, 1381 (M.D. Ga. 2004) (noting that "[i]t is clear that Georgia courts would find the 'learned intermediary rule' encompasses any fraud, fraudulent concealment, misrepresentation, failure to barn or breach of warranty claims."); *Doe v. Solvay Pharms., Inc.*, 350 F. Supp. 2d 257, 272-74 (D. Maine 2004) (applying the learned intermediary doctrine and granting summary judgment as to plaintiff's causes of action for strict liability, failure to warn, and fraudulent misrepresentation, reasoning that "[a]t its heart, Ms. Doe's claim is a failure to warn claim.").

where the plaintiffs' implanting surgeons had not read the subject mesh products' directions for use. Because such facts break the chain of causation under the learned intermediary doctrine, the Court granted summary judgment in favor of the defendant manufacturers. In *Lewis v. Ethicon, Inc.*, the Court found that "[t]he plaintiffs must proffer some evidence that [the manufacturer's] allegedly deficient warnings caused [plaintiff's] injuries. Without evidence that [the physician] relied on the warnings in the [D]FU or the patient brochures, the plaintiffs cannot carry their burden at the summary judgment stage." No. 2:12-cv-04301, at *8 (S.D. W. Va. Jan. 15, 2014) (ECF No. 194).

In both *Lewis* and *Jones v. C.R. Bard, Inc.*, No. 2:11-cv-00114 (S.D. W. Va. June 4, 2013) (ECF No. 288), this Court rejected various allegations from plaintiffs regarding subjects such as the MSDS and rates of complications, connected with "testimony from [the doctor] regarding information that [s]he was not provided and that, had [s]he known about such information, [s]he would not have used the [] product." *Id.* at *11. Without evidence the doctor actually read the DFUs, such allegations are unavailing:

> [T]he plaintiff never directly responds to Bard's argument that Dr. Williams simply never read the IFU. Dr. Williams's testimony essentially suggests that he felt he knew enough about the risks of implanting meshes such that he did not need to read the IFU. Accordingly, even drawing the facts and inferences in the light most favorable to the plaintiff, as the standard for a motion for summary judgment requires, I cannot find that the plaintiff has offered sufficient evidence to meet her burden of showing that additional or different warnings would have prevented Dr. Williams from implanting the Avaulta product into her. Simply put, because Dr. Williams did not review the IFU, no amount of warnings contained in it would have caused Dr. Williams to act any differently.

Id. at *19-20; s*ee also Lewis*, No. 2:12-cv-04301, at *8.

For these same reasons, Plaintiff's claims also fail here. Dr. Fogarty's testimony confirms he did not rely on the Advantage DFU for warnings when he made the medical judgment to use the Advantage in Ms. Foreman's surgery. (SOMF Nos. 13-15 and 17.) When asked if he relied on marketing materials in making medical decisions, Dr. Fogarty testified that he did not. (SOMF No. 18.) Dr. Fogarty instead relied on his own clinical experience and medical training when determining the benefits and risks of placing the Advantage in Ms. Foreman. (SOMF No. 17.)

Regardless, Boston Scientific's DFU warned against the very risks about which Plaintiff complains. Here, as a result of the implantation of the Advantage, Ms. Foreman alleges she has suffered from urinary incontinence, general pain, pain with intercourse, mesh exposure, vaginal shrinkage and bowel problems. (SOMF No. 26.) However, the DFU for the Advantage contains warnings related to each of these complaints. The Advantage DFU specifically warns about the following: "vaginal erosion/extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, and inflammation," which could require removal of the entire mesh; "[e]xcess tension may cause temporary or permanent lower urinary tract obstruction and retention;" risks of pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder, pelvic and vaginal pain, dyspareunia, vaginal bleeding, and vaginal discharge. (SOMF Nos. 8 and 9.) The Advantage DFU also warns of the following Potential Complications: irritative voiding symptoms including urgency and urge incontinence, infection, pelvic and vaginal pain, urinary retention, dyspareunia, vaginal bleeding, vaginal discharge, erosion of the vaginal or urethral mucosa or bladder wall, and recurrent stress urinary incontinence. (SOMF No. 10.)

Plaintiff cannot show that any alleged inadequacy in Boston Scientific's warnings concerning the Advantage device caused her alleged injuries. Changes to the DFU to cure any alleged deficiency would not have altered Dr. Fogarty's medical decision to implant the device because he did not rely on it. *Lewis*, No. 2:12-cv-04301, at *8 ("Without evidence that [the physician] relied on the warnings in the [D]FU or the patient brochures, the plaintiffs cannot carry their burden at the summary judgment stage."). Plaintiff failed to proffer any evidence that Dr. Fogarty relied on the warnings in the device DFU. Accordingly, summary judgment should be granted on Plaintiff's warning claims.

2. Plaintiff's Warnings Claims Fail under the Sophisticated User Doctrine.

In California, the sophisticated user defense exempts manufacturers from their typical obligation to provide product users with warnings about the products' potential hazards. *Johnson v. Am. Standard, Inc.*, 179 P.3d 905, 910 (Cal. 2008). The doctrine serves to relieve the manufacturer of its duty to warn. *Id.* The rationale supporting the defense is that "the failure to provide warnings about risks already known to a sophisticated purchaser usually is not a proximate cause of harm resulting from those risks . . . . [T]his is because the user's knowledge of the dangers is the equivalent of prior notice." *Id.* at 911. Because these sophisticated users are charged with knowing the particular product's dangers, the failure to warn about those dangers cannot be the legal cause of any harm that product may cause. *Id.* at 910-11.

Significantly, under the sophisticated user doctrine, the duty to warn is measured "by what is generally known ***or should have been known*** to the class of sophisticated users, rather than by the individual plaintiff's subjective knowledge." *Id.* at 911, 919-20 (emphasis added). The inquiry is therefore objective in nature. *Id.* The relevant time for determining user sophistication is the time of injury and when the user knew or should have known of the risk. *Id.*

at 916. The doctrine has been applied to various users and types of products, including medical devices. *See, e.g., Crayton v. Rochester Med. Corp.*, 1:07-CV-1318 OWW GSA, 2011 WL 475009 (E.D. Cal. Feb. 4, 2011) (unpublished), *aff'd*, 548 F. App'x 483 (9th Cir. 2013) (unpublished). The defense applies equally to strict liability and negligent failure to warn claims. *Johnson*, 179 P.3d at 911.

In *American Standard*, an HVAC technician asserted product liability claims against an air conditioning equipment manufacturer after developing pulmonary fibrosis, alleging the manufacturer failed to warn that servicing its product would expose the plaintiff to harmful gas. *Am. Standard*, 179 P.3d at 908-10. In affirming the trial court's grant of summary judgment in favor of the product manufacturer, the California Supreme Court found the evidence indisputably showed that HVAC technicians could reasonably be expected to know of the hazards the plaintiff complained the defendant failed to warn against. *See id.* at 916. The Court concluded the sophisticated user defense "should apply in this case to defeat all causes of action for defendant's alleged failure to warn." *Id.*

Similarly in *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 (Cal. App. 1992)), the court affirmed summary judgment for an intrauterine device (IUD) manufacturer sued for product liability after the decedent died from a pelvic infection. *Id.* at 352. The manufacturer had offered "its physician package insert which advised of the risk of pelvic infection," *id.* at 361, and an expert opinion that "the risk of pelvic infection from the insertion of an IUD was well known in the medical community." *Id.* at 362. The plaintiffs offered an expert opinion that the warnings were still "inadequate because they did not specifically advise of the risk of death which can result from a pelvic infection." *Id.* But the manufacturer countered "that the risk of death from any untreated infection was a matter of general and elemental medical knowledge." *Id.*

The California Court of Appeal held the manufacturer was entitled to summary judgment because it showed the undisclosed risk of death was ascertainable to the medical community: physicians already knew IUDs could cause pelvic infections, and they knew untreated pelvic infections could cause death. *Id.* at 362. No triable issue existed, therefore, as to the medical community's ability to conclude IUDs posed a risk of death through untreated pelvic infections. The court reasoned: "We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the consumer, in this case the physician. Further, if the risk of death from untreated infection is universally known in the medical profession, the failure to warn the physician of that risk cannot be the legal cause of the decedent's death." *Id.*

Similarly here, Dr. Fogarty was already knowledgeable of the risks Ms. Foreman complains Boston Scientific failed to warn against. (SOMF No. 16.) At a very minimum, Dr. Fogarty should have known of the dangers the Advantage product presented. *See Johnson*, 179 P.3d at 911, 919-20; *see also* 2008 FDA Public Health Notification. Because Dr. Fogarty knew or should have known of the very dangers Plaintiff allege Boston Scientific failed to warn against, summary judgment is warranted pursuant to the sophisticated user doctrine.

d. Plaintiff Cannot Establish Causation Under Any Product Defect Theory.

Under either a negligence or a strict liability theory of products liability, a plaintiff must prove that the alleged defect caused the claimed injury. *Merrill v. Navegar, Inc.*, 28 P.3d 116, 124 (Cal. 2001); *Stephen v. Ford Motor Co.*, 134 Cal. App. 4th 1363, 1373 (2005) (plaintiff must show a substantial probability that the defect, and not something else, caused the plaintiff's injury). Here, Plaintiff cannot show that the specific defect complained about was the specific cause her injuries. As such, summary judgment is appropriate.

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II. PLAINTIFF'S BREACH OF WARRANTY CLAIMS FAIL

a. Plaintiff's Warranty Claims Fail for Lack of Notice.

As indicated, the learned intermediary doctrine bars Plaintiff's breach of express and implied warranty claims. But Plaintiff's warranty claims also fall on their own accord for lack of proof. To recover for breach of a warranty, California law requires Plaintiff provide Boston Scientific pre-suit notice of the breach. Section 2607 of the California Commercial Code mandates that "[t]he buyer must, within a reasonable time after he or she discovers or should have discovered any breach, notify the seller of breach or be barred from any remedy." CAL. COM. CODE § 2607; *see also Mance v. Mercedes-Benz USA*, 901 F. Supp. 2d 1147, 1153 (N.D. Cal. 2012) ("A plaintiff must also plead that he or she provided the defendant with pre-suit notice of the breach.") (citing CAL. COM. CODE § 2607). Plaintiff has the burden of proving reasonable notice. *Cardinal Health 301, Inc. v. Tyco Electronics Corp.*, 87 Cal. Rptr. 3d 5, 21 (Cal. Ct. App. 2008). Whether notice was properly given "may be determined as a matter of law." *Id.* Because Plaintiff were required to give pre-suit notice to Boston Scientific and did not, the Court must grant Boston Scientific's motion for summary judgment on Plaintiff's warranty claims.

b. Plaintiff's Warranty Claims Fail For Lack of Privity with Boston Scientific.

Even if the Court finds Plaintiff has somehow satisfied the notice requirement, Plaintiff has not and cannot prove privity with Boston Scientific, as required to maintain a cause of action for breach of express or implied warranty claims in the medical device context. *See Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 788 (Cal. Ct. App. 1994) (no implied warranty claim where plaintiff "relied upon his physician's skill or judgment to select or furnish a suitable product"). With medical devices, warnings and descriptions are directed to the

physician, not the patient or plaintiff. *Valentine*, 68 Cal. App. 4th at 1483 (patient is presumed to have learned "through the physician . . . of the properties and proper use of the . . . implant"); *see also Sherman v. Stryker Corp.*, No. 09-cv-224, 2009 WL 2241664, at *4. (C.D. Cal. Mar. 30, 2009). This is because physicians "appreciate the fact that all prescription medical products involve inherent risks, known and unknown," and they do not expect that such products are without such risks. *Brown*, 44 Cal. 3d at 1049. Therefore, any warranty, assuming there is one, must be evaluated as between Boston Scientific and Ms. Foreman's physician.

In *Currier v. Stryker Corp.*, No. 2:11-CV-1203, 2011 WL 4898501 (E.D. Cal. Oct. 13, 2011), a California federal court concluded no basis existed for the plaintiff's breach of warranty claim because the plaintiff necessarily relied on her physician:

> Because this is a medical implant case, and the [complaint] alleges that the product was surgically inserted in a hospital, the Court cannot plausibly infer from the [complaint] that Plaintiff relied on anything other than his physician's skill and judgment in selecting the . . . product, nor that any purchase of the product was based on a warranty from the manufacturer to Plaintiff. The Court cannot plausibly infer that there is a relationship between the Defendants and Plaintiff that would allow Plaintiff to state a breach of warranty claim.

Id. at *4; *see also Adams v. I-Flow Corp.*, No. 09-cv-9550, 2010 WL 1339948, at *4 (C.D. Cal. Mar. 30, 2010) (dismissing plaintiffs' claims because the complaint was simply "devoid of any facts suggesting that plaintiffs relied upon anything other than their physicians' skill and judgment in selecting and prescribing the [drugs and devices]" and finding that "in the context of prescription medical devices and pharmaceuticals, the transaction is between the manufacturer and the physician, not the patient.").[12]

[12] Both *Currier* and *Adams* cite *Blanco*, 158 Cal. App. 4th at 1058-59.

Under the reasoning of these decisions, it is the physician who reviews the warnings and selects particular devices to implant, and thus determines whether the proposed application is "fit for ordinary purposes for which such [devices] are used." It is also the physician's "skill or judgment" that matters in determining which device should be implanted for each patient based on her unique needs. Accordingly, a patient's claim for breach of implied warranty is not cognizable because the patient lacks the privity required to assert such a claim. *Blanco*, 158 Cal. App. 4th at 1058-59 (holding that breach of warranty claims against a medical device manufacturer are improper due to lack of privity between patient and manufacturer); *see also Evraets*, 29 Cal. App. 4th at 788.

Here, Plaintiff's warranty claims are barred because privity did not exist between Boston Scientific and Ms. Foreman. Moreover, Ms. Foreman did not rely on Boston Scientific's representations about what medical devices were appropriate for her. Rather, Ms. Foreman relied on Dr. Fogarty's skill and judgment in choosing whether to use synthetic pelvic mesh and, if so, which product. *Blanco*, 158 Cal. App. 4th at 1058-59. Plaintiff testified that she trusted Dr. Fogarty's recommendation of the Advantage mesh. (SOMF Nos. 20 and 21.) In this context, because it is the physician who selects the product, any privity is between the seller and the physician. *Blanco*, 158 Cal. App. 4th at 1058. For these reasons, the Court should enter summary judgment in favor of Boston Scientific on Plaintiff's claims for breach of express and implied warranties.

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CONCLUSION

For all of the foregoing reasons, Boston Scientific respectfully requests this Court grant its Motion for Summary Judgment on Plaintiff's claims.

Dated: January 14, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2015, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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